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RECORD OF ORAL HEARING  
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Appeal 2010-008567  
Application 10/564,096  
Technology Center 1600

Oral Hearing Held: Thursday, October 20, 2011

Before DONALD E. ADAMS, DEMETRA J. MILLS and  
ERIC B. GRIMES, Administrative Patent Judges

ON BEHALF OF THE APPELLANT:

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Appeal 2010-008567  
Application 10/564,096

1                   *The above-entitled matter came on for hearing on Thursday,*  
2                   *October 20, 2011, commencing at 9:15 a.m., at the U.S. Patent and*  
3                   *Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room A,*  
4                   *Alexandria, Virginia, before Jan Jablonsky, Notary Public.*

5  
6                   USHER: Calendar 44, Appeal 2010-8567, Mr. Gron.  
7                   (Discussion held off record.)

8                   JUDGE ADAMS: Good morning, Mr. Gron.

9                   MR. GRON: Good morning.

10                  JUDGE ADAMS: We are familiar with the record. You will  
11                  have 20 minutes. And just some housekeeping, before we start.

12                  Can you start with claim interpretation?

13                  MR. GRON: I will.

14                  JUDGE ADAMS: Okay.

15                  MR. GRON: Thank you.

16                  May it please the Board. Claims have been rejected under 103,  
17                  basically over Watts. In 102, Claim 34 has been rejected, 102 over  
18                  Shimono.

19                  I believe the Examiner's error in this case is that he refuses to  
20                  look at any of the evidence, and basically says, "Chitosan is chitosan, and if  
21                  chitosan has this type of properties, therefore in the composition it must still  
22                  have those type of properties."

23                  We believe that that's an error in this particular case.

24                  Let me go through the claim interpretation, first of all. I want  
25                  to talk about Claim 1. Because in Claim 1, we have a form, which has  
26                  micro-pellets in there;

27                  And it has an inner matrix. And it consists essentially of the  
28                  mucoadhesive polymer, and embedded therein, the peptide or active peptide  
29                  or protein.

30                  Then it has an outer film layer, which --

31                  JUDGE ADAMS: If I can interrupt?

32                  The inner matrix in Claim 1?

1 MR. GRON: Yes.

2 JUDGE ADAMS: Does that permit the presence of gelatin?

3 MR. GRON: The presence of what?

4 JUDGE ADAMS: Gelatin.

5 MR. GRON: It does not. And the reason is, Your Honor,  
6 because the art of record -- and I cite to you the Shaheen article, I cite to you  
7 Watts himself, and I cite to you EP13753 of record, which indicates and  
8 teaches clearly that gelatin is a bio-adhesive;

9 Which means that it binds to the membrane -- I'm going to try  
10 and be very careful with the language here -- binds to the membrane in the  
11 intestines;

12 As opposed to a mucoadhesive, which binds to the mucus that's  
13 outside the membrane.

14 Now this is critical today, because one of the significant  
15 problems with delivering drugs to the intestines is the fact that when the  
16 drug is binded and retained, as it is in Watts, for example, on the membrane  
17 for extensive periods of time, what happens is it becomes irritating;

18 It becomes infective, it collects bacteria. And therefore, you get  
19 an infection, irritation, problems down in the intestines, which you don't  
20 want.

21 On the other hand, if you have a mucoadhesive, every time you  
22 drink something, have a soda, whatever, it washes the mucus out, and the  
23 drug with it.

24 Therefore, it's not collected on the membrane, it doesn't irritate  
25 the body. And you can add in the next period another small amount of the  
26 drug, and then treat it again, and then wash it out again;

27 And therefore, you don't have all these infections, irritations, et  
28 cetera. This is why it's very important.

29 JUDGE ADAMS: So explain to us how Claim 33 further limits  
30 Claim 1.

31 MR. GRON: Claim 33 or 34, Your Honor?

32 JUDGE ADAMS: Thirty-three.

1 MR. GRON: Thirty-three? Well, it specifically says it just  
2 doesn't have gelatin.

3 JUDGE ADAMS: So the intent there is?

4 MR. GRON: The intent there is that that is a particular  
5 bioadhesive, which is not in there. Other bioadhesives are known -- as  
6 Shaheen teaches, there is a variety of other bioadhesives.

7 We don't want any of them in there.

8 And the reason is: As Watts points out -- and I'll take you to --

9 JUDGE ADAMS: So in the context of Claim 1, when you say  
10 "consisting essentially of a mucoadhesive polymer, having a mucoadhesive  
11 effect, with some active agent embedded into it," within the scope of those  
12 mucoadhesive polymers, you're excluding one of them that might fall out  
13 from the "consisting essentially of" language, one of them being gelatin.

14 Is that the idea?

15 MR. GRON: You're excluding gelatin. Exactly.

16 Any material which binds to the membrane itself. And the art  
17 teaches gelatin is definitely one.

18 JUDGE ADAMS: Yeah.

19 MR. GRON: All right.

20 Moreover, Watts shows that -- and teaches -- let me get a hold  
21 of Watts here, I'm looking (examining document).

22 And I would take you to, I believe first of all, column seven.  
23 And column seven of Watts, the first four lines, and it says:

24 "The compositions" -- and we're talking about compositions of  
25 gelatin and chitosan, because that's the invention in Watts, the  
26 composition -- it says, "it gels to the mucosa."

27 Therefore, it's binding to the membrane.

28 Now to show that that's different, look at column four. And in  
29 column four, Watts indicates the surprising effect of the combination. Is  
30 says, that:

31 "In fact, the combination presents itself in the intestines in a  
32 more effective way than either gelatin or chitosan," which suggests to

1 persons skilled in the art, if it's more effective than gelatin, it's definitely  
2 going to be a bioadhesive.

3 Our claims exclude the combination of chitosan and gelatin in  
4 the matrix.

5 Now the Examiner says, "Well, the matrix still has chitosan in  
6 it, in Watts, and therefore, it must have a mucoadhesive effect."

7 That's not what Watts teaches. Watts teaches it apparently  
8 binds, and it's much more effective than either gelatin or chitosan.

9 And if it's more effective than gelatin, that means it's definitely  
10 binding to the intestines. We don't want that. We don't claim that.

11 JUDGE GRIMES: Is there any evidence that the bioadhesive  
12 character that you're positing would interfere with the mucoadhesive  
13 property of --

14 (Simultaneous conversation.)

15 MR. GRON: Well, in fact, Your Honor, there is some binding.  
16 The mere fact that you have a bioadhesive effect doesn't mean  
17 that there is not some binding. It's just that it's readily washed out.

18 Now, let me point out --

19 JUDGE GRIMES: I'm sorry. Could you go over that again? I  
20 didn't follow that.

21 JUDGE ADAMS: I think you meant to say "mucoadhesive  
22 effect" instead of bioadhesive effect.

23 MR. GRON: I'm sorry. But I --

24 JUDGE ADAMS: So let me give you a hypothetical.

25 MR. GRON: All right.

26 JUDGE GRIMES: If you had a mixture of 50 percent of  
27 chitosan and 50 percent of gelatin --

28 MR. GRON: Right --

29 JUDGE GRIMES: You're arguing that the gelatin would give it  
30 a bioadhesive character?

31 MR. GRON: The combination gets to the chitosan an overall  
32 bioadhesive effect, yes.

1 JUDGE GRIMES: But is there any evidence that it wouldn't  
2 also have mucoadhesive properties? In that mixture of 50/50?

3 MR. GRON: Well, mucoadhesive properties, mucoadhesive  
4 effect, as defined in the specification, means that it increases the viscosity of  
5 the combination of the material and mucus.

6 And your question, again, Judge Grimes, is?

7 JUDGE GRIMES: My question is, basically, is there any  
8 evidence that the gelatin, the bioadhesive property of the gelatin, is going to  
9 interfere with the normal mucoadhesive property of the chitosan?

10 MR. GRON: Watts himself says that you get a greater strength  
11 and a greater presentation to the membrane, a combination, than either  
12 gelatin or chitosan.

13 This suggests that the combination binds, definitely binds, and  
14 that the combination is not washed out. It's retained.

15 Watts says it's retained for, at minimum, eight hours. This is  
16 not what we want.

17 JUDGE GRIMES: It's not a question of what you want, it's a  
18 question of what your claim reads on --

19 MR. GRON: Sorry, Your Honor --

20 JUDGE GRIMES: Is the product --

21 MR. GRON: All right. Now --

22 JUDGE ADAMS: Let's stay with column four of Watts.

23 MR. GRON: All right.

24 JUDGE ADAMS: Tell me what it is, exactly, that leads you to  
25 this argument that the combination of chitosan and gelatin is bioadhesive, as  
26 opposed to just binding the mucosal surface.

27 MR. GRON: Because it says the effect is superior to that of  
28 gelatin itself. And gelatin itself, as recognized in the prior art, has a  
29 bioadhesive effect.

30 JUDGE ADAMS: Two lines above that, it says "The improved  
31 presentation of vaccines to mucosal surfaces." Now a mucosal surface is the

1 membrane or the mucus, yada, yada, ya, "to an extent that such an effect is  
2 superior to that obtained by chitosan solution or gelatin."

3 So what's leading us to read this as "bioadhesive," as opposed  
4 to it's the combination of these two ingredients, one which you allege is a  
5 bioadhesive, and chitosan, which is a mucoadhesive?

6 It's binding a mucosal surface.

7 MR. GRON: Well, if it has a greater effect on the mucosal  
8 surface than does the gelatin, and it's recognized in the art that gelatin has a  
9 bioadhesive effect; therefore, you would expect that the combination has a  
10 greater bioadhesive effect than --

11 (Simultaneous conversation.)

12 JUDGE ADAMS: Well, it has a greater effect, compared to  
13 chitosan or gelatin. All right?

14 MR. GRON: But --

15 JUDGE ADAMS: So chitosan has its function.

16 MR. GRON: Right.

17 JUDGE ADAMS: It's a mucoadhesive. Gelatin has its  
18 function, it's a bioadhesive. I think what the Examiner is saying is chitosan  
19 is still acting as a mucoadhesive. It's just when I put them together, they  
20 have these combined properties.

21 Gelatin is acting the way gelatin acts, and chitosan's acting the  
22 way --

23 (Simultaneous conversation.)

24 MR. GRON: It says in the column seven that we're, in fact,  
25 creating a gel on the mucosa.

26 JUDGE ADAMS: So chitosan doesn't form a gel?

27 MR. GRON: Chitosan, not with the membrane. It forms it with  
28 the mucus. And binding to the membrane is indirect to the --

29 JUDGE ADAMS: I'm just not seeing how this idea, this  
30 concept that you're forming a gel, is relevant to your argument.

31 Right?

32 MR. GRON: It would suggest --



1 JUDGE ADAMS: Whether it forms a gel or not -- I mean, you  
2 can form the gel and bind the mucosa, it can form a gel and be a  
3 bioadhesive.

4 What difference does it make?

5 MR. GRON: The suggestion in Watts is that there is binding.  
6 And our claims do not, because of the consisting essentially of language,  
7 exclude any material which would be bioadhesive, like gelatin.

8 JUDGE ADAMS: Okay. Let's contrast with Claim 34.

9 MR. GRON: Thirty-four, yes.

10 JUDGE ADAMS: So in Claim 1, you have an intermatrix  
11 layer. Now I'm getting to this idea of, where we talking about concentric  
12 circles?

13 MR. GRON: Right.

14 JUDGE ADAMS: Or are we talking about something that's all  
15 mixed up?

16 So in Claim 1, we have this intermatrix layer, that consists  
17 essentially of a mucoadhesive polymer, into which is imbedded an active  
18 substance.

19 MR. GRON: Right.

20 JUDGE ADAMS: So that would seem to suggest it's not a  
21 concentric circle, and that there's something --

22 (Simultaneous conversation.)

23 MR. GRON: Exactly.

24 JUDGE ADAMS: Okay.

25 In Claim 34, we don't have that extra language about the active  
26 substance --

27 (Simultaneous conversation.)

28 MR. GRON: No, you have just the mixture.

29 JUDGE ADAMS: So why would that compel us to read on just  
30 the mixture, as opposed to a --

31 (Simultaneous conversation.)

1 MR. GRON: And that's why I bring up Your Honors, the most  
2 recent In re Suitco Surface, Inc. And that's at 603 -- from 603 at 1260,  
3 where it says:

4 "The PTO's construction here, though certainly broad, is  
5 unreasonably broad.

6 "The broadest construction rubric, coupled with the term,  
7 'comprising' does not give the PTO an unfettered license to interpret claims  
8 to embrace anything remotely related to the claimed invention.

9 "Rather, claim should always be read in light of the  
10 specification."

11 If, in fact, we add a bioadhesive to that composition, we don't  
12 have a mucoadhesive effect.

13 JUDGE ADAMS: Well, first, let's start with the idea of what  
14 are we talking about with regard to an inner matrix in Claim 34?

15 Are we talking about concentric circles, where you start with  
16 the bead, coat it with --

17 (Simultaneous conversation.)

18 MR. GRON: In light of the specification, that's what we would  
19 be talking about, yes.

20 JUDGE ADAMS: We would talk about a concentric circle.

21 MR. GRON: Right.

22 JUDGE ADAMS: We wouldn't talk about an inner matrix  
23 that's a mixture of a pharmaceutical agent, along with a mucosal agent.

24 Is that --

25 MR. GRON: Well, yes. That inner matrix is the inner circle.

26 Normally, there's a core, and then around it, there is a -- you can  
27 either have it as the core itself, or the inner matrix is the first --

28 (Simultaneous conversation.)

29 JUDGE ADAMS: Well, to make sure we're talking apples and  
30 apples, let's compare Claim 34 against the Shimono reference. Right?

31 MR. GRON: Yes.

1                   And I would point the Board in Shimono to Figure 11. Because  
2 that's where --

3                   JUDGE ADAMS: No, let's go straight to the example.

4                   MR. GRON: Which example --

5                   JUDGE ADAMS: Example six. It's on page seven, right-hand  
6 column, lines 40-ish plus.

7                   MR. GRON: Oh, column 11?

8                   JUDGE ADAMS: Paragraph 47, column 12.

9                   MR. GRON: Column 12 (examining document).

10                  JUDGE ADAMS: Paragraph 47, right at the bottom.

11                  MR. GRON: Forty-seven. Yes, Your Honor.

12                  JUDGE ADAMS: So we start off in paragraph 47, as I'm  
13 understanding this, with a pellet.

14                  MR. GRON: Right.

15                  JUDGE ADAMS: Right. And on that pellet, we coat  
16 acetaminophen.

17                  MR. GRON: Correct.

18                  JUDGE ADAMS: And on that acetaminophen coating, we add  
19 another layer.

20                  MR. GRON: Right. Another layer.

21                  JUDGE ADAMS: That has chitosan.

22                  MR. GRON: Right, but the layer also --

23                  JUDGE ADAMS: Well, let's just stay with -- we're trying to  
24 get to how this claim should be interpreted.

25                  MR. GRON: Yes.

26                  JUDGE ADAMS: So right now we have a pellet with a layer of  
27 acetaminophen, the drug. On top of that drug, we have another layer that's  
28 chitosan.

29                  MR. GRON: Right.

30                  JUDGE ADAMS: And then if you look at the next paragraph,  
31 48, to make it something that's effective for delivery to the colon we add an  
32 outer surface layer.

1 MR. GRON: Correct.

2 JUDGE ADAMS: Does your inner matrix permit this layering  
3 effect, these concentric circles? Or is the chitosan --  
4 (Simultaneous conversation.)

5 MR. GRON: In light of our specification, it is a concentric  
6 build-up, yes.

7 JUDGE ADAMS: But is it a concentric build-up of pellet inner  
8 matrix, outer matrix? Or is it a concentric circle of pellet, drug, chitosan,  
9 outer matrix?

10 MR. GRON: It would be: Inner matrix and outer coating. The  
11 inner matrix would have the protein drug and the mucoadhesive material.

12 JUDGE ADAMS: Do they have to be mixed together? Or can  
13 they be just another layer?

14 MR. GRON: It would appear that you have 40 percent of less  
15 of the active ingredient and the polymer. There's nothing that is more than  
16 one layer.

17 Now that's what the Examiner says.

18 JUDGE ADAMS: Well, that's what I'm getting at.

19 MR. GRON: Oh, oh.

20 (Laughter.)

21 MR. GRON: Yeah. But the point being, however -- that's why  
22 I direct your attention to column four.

23 JUDGE ADAMS: Right.

24 MR. GRON: If you see, there is also a water-insoluble  
25 polymer, in which the --

26 JUDGE ADAMS: Are you referring to Figure 11 now?

27 MR. GRON: I'm sorry, did I say four? I apologize. Figure 11.

28 Figure 11, it has the drug in the core. Around it is a layer of  
29 water-insoluble polymer, in which there is embedded, or dispersed, chitosan.  
30 And then an outer enteric layer.

1           Now we know it's in Claim 34 -- and I believe you go down  
2 about eight lines, where it says, "Wherein the particles do not have a layer  
3 separating the inner matrix and outer coating."

4           That language designed to eliminate that middle layer that we  
5 have in Shimono.

6           JUDGE ADAMS: But I think the Examiner's interpretation is  
7 that the inner matrix of your claim is the core, the -- containing solid  
8 material, plus the layer that has -- insoluble polymer.

9           (Simultaneous conversation.)

10          MR. GRON: Exactly. The Examiner seems to vary the matrix  
11 at will. Any number of layers can be the matrix. The outermost layer is the  
12 outermost layer.

13          That's an interesting interpretation, but it's totally inconsistent  
14 with what we have in the specification.

15          JUDGE GRIMES: Show me where it's inconsistent with the  
16 specification.

17          MR. GRON: Well, because we say a matrix layer. I will give  
18 you one example.

19          Page six.

20          JUDGE GRIMES: Right, you define the inner matrix layer at  
21 page six.

22          (Simultaneous conversation.)

23          JUDGE GRIMES: -- says you can't have layers.

24          MR. GRON: Right. Inner matrix layer, and then an outer  
25 layer.

26          JUDGE ADAMS: So your argument would be, since we use  
27 the term, "layer" singular, you can't have multiple layers and call it an inner  
28 matrix?

29          MR. GRON: Well, it's only consistent with the specification.

30          The Examiner seems to think that you can take -- based on that,  
31 Your Honor, you could say the inner matrix comprises both the inner matrix

1 and the outer coating and the air around it would be the -- I mean, that of  
2 course, is somewhat extreme;

3 And Suitco would say -- Judge Rader would say, "Please,  
4 please don't make the interpretation that broadly, because that's not what the  
5 specification teaches."

6 Moreover, that's not our function. We would be completely  
7 defeated.

8 That chitosan powder appears to create pores in a  
9 water-insoluble polymer, so that you can now leach out the drug. That's  
10 what appears to be happening there.

11 There appears to be no binding whatsoever of the chitosan to  
12 the membrane or to the mucus at all.

13 It's in a water-insoluble polymer. And it retains that drug and  
14 delivers it over an extended period of time -- according to the specification,  
15 according to Shimono's teaching -- which indicates that there is, in effect, no  
16 binding and ability to wash out, whatsoever.

17 That's all it's doing is in effect, creating holes, so that the drug  
18 could apparently leach out.

19 Or, it's possible there is some interaction between that  
20 water-insoluble polymer and the chitosan, such that you would create a  
21 gel-type material, which would be a bioadhesive.

22 I don't know what's going on there. I can't figure it out. The  
23 only thing I know is it's inconsistent with the teaching in our specification.

24 And in fact, it appears to have a layer separating what we regard  
25 as this inner matrix from the outer matrix. And there appears to be no  
26 delivery by no mucoadhesive effect shown by the chitosan for the drawing.

27 The whole point of this chitosan is that it sort of carries the  
28 material to the membrane.

29 JUDGE ADAMS: I understand. We're just having a little bit of  
30 concern about how to interpret inner matrix.

1 MR. GRON: Well, the Examiner -- one of the errors in his case  
2 is the Examiner refuses to consider any of this. He won't look at the fact that  
3 gelatin's a bioadhesive.

4 We point to the various aspects of the specification that show  
5 that the mixture of gelatin and chitosan is different from gelatin or chitosan.

6 That means nothing to him.

7 We've shown that there is that inner layer and it's a  
8 water-soluble polymer. We point to all these factors. The Examiner says,  
9 "Chitosan is chitosan. I'm sorry, game over."

10 It's tough to respond to this.

11 Let's go further.

12 JUDGE ADAMS: So other than page six, is there any other  
13 definition of "inner matrix layer" in your specification?

14 MR. GRON: Other than page six? No doubt, Your Honor, but  
15 that's the one I went to immediately.

16 JUDGE ADAMS: Okay.

17 MR. GRON: Now let me go further.

18 JUDGE ADAMS: I think I was hearing you say that if you mix  
19 the chitosan with the water-insoluble polymer, as in Shimono, you're not  
20 going to get the mucoadhesive effect that's required by your claims.

21 Was that --

22 MR. GRON: That's correct.

23 JUDGE ADAMS: And it's the whole focus of your  
24 specification?

25 MR. GRON: That's the whole focus of the spec, exactly.

26 That's the problem with Shimono. Shimono's got it mixed with  
27 that water-insoluble polymer.

28 It appears to be because if you look at the way that those  
29 particles are evenly dispersed, it appears to be that, once the outer membrane  
30 is broken, there is a tack by the aqueous fluids on the surface, and it starts  
31 building little pores through, so that it eventually lets the drug out through  
32 the pores.

1                   That appears to be what's going on. I can't tell.

2                   And I'm sorry, Your Honors, we want to go where that pill  
3 goes, so that we can take pictures. So --

4                   The last bit I would like to talk about for a moment is the  
5 allegation of new matter in Claim 34. Because of the fact that we said in  
6 limitation "Do not have a mucoadhesive lipophilic matrix."

7                   Well, at page 3738 in the bridging paragraph --

8                   JUDGE GRIMES: Of your specification?

9                   MR. GRON: Of the specification, yes. It indicates that what  
10 we don't want is an interpretation between the mucoadhesive polymer and  
11 the lipophilic-type material.

12                  JUDGE ADAMS: I don't have an argument with your  
13 specification disclosing a lipophilic matrix.

14                  MR. GRON: Right.

15                  JUDGE ADAMS: I think what the Examiner is saying is, "I  
16 have a concern that you never described a mucoadhesive lipophilic" --

17                  MR. GRON: I believe that's exactly what the Examiner is  
18 saying. But that paragraph suggests that there is some sort of an  
19 interpretation going on, and we don't want that.

20                  And so when we say it does not have a mucoadhesive lipophilic  
21 matrix, what we don't want is any type of that interaction.

22                  That's what I believe that information -- that particular  
23 paragraph says "In order to control uncontrollable interactions," so there  
24 apparently can be interactions.

25                  And so when we say we do not have a mucoadhesive lipophilic  
26 matrix, basically we don't have that type of interactions. And I can't see why  
27 that appears to be new matter, recently.

28                  Just go back to the fact that -- and I'll summarize that that inner  
29 matrix layer consists essentially of the mucoadhesive polymer. That should  
30 exclude any material, which causes the combination to act as a bioadhesive,  
31 or any bioadhesive-type material.

32                  JUDGE ADAMS: Where are you reading from, then?



1 MR. GRON: Claim 1.

2 JUDGE ADAMS: Okay.

3 MR. GRON: All right. Claim 1. That should exclude any  
4 material, which alters the characteristics and properties. And --

5 JUDGE ADAMS: And just building on that, in Claim 33, is  
6 one of those that alters the properties --

7 (Simultaneous conversation.)

8 MR. GRON: Is one of those, exactly. And that's why it's out.

9 Hmm, we indicate that we defined at the bottom what the  
10 mucoadhesive effect is. In fact, it's an increase in the viscosity.

11 And all the other aspects of the invention are  
12 essentially -- they're known for other drugs. And we're not alleging that  
13 they're not known for other drugs.

14 The fact is, however, none of them work together.

15 There appears to be an interaction -- and I don't think even the  
16 inventors know -- between the protein or the peptide and the materials which  
17 are specified in the claim, which materials had the mucoadhesive effect.

18 That's at the very bottom.

19 We added those materials because we didn't want a vague  
20 interpretation as to maybe we really didn't know what those materials that  
21 have a mucoadhesive effect were, so we added all the materials at the  
22 bottom.

23 So it's absolutely clear what those materials are.

24 One of the materials, which it is not is gelatin. And it is  
25 definitely not, according to the prior art of record, a combination of at least  
26 50 percent gelatin and chitosan.

27 JUDGE ADAMS: Now when we looked at Claim 34 --

28 MR. GRON: Thirty-four --

29 JUDGE ADAMS: We just have this composition that  
30 comprises a pharmaceutical ingredient and a polymer that has a  
31 mucoadhesive effect.

32 It doesn't exclude gelatin, does it?

1           MR. GRON: If we put gelatin in, our polymer, which has a  
2           mucoadhesive effect, no longer has, as a mucoadhesive. In which case, we  
3           have nothing in there, that has a mucoadhesive effect.

4           JUDGE ADAMS: And you're drawing that conclusion from  
5           column four and seven of Watts?

6           MR. GRON: Of Watts.

7           I realize this is not the easiest case, Your Honors. And but  
8           they're not all easy (laughing).

9           Are there any further questions?

10          JUDGE ADAMS: Any questions?

11          JUDGE GRIMES: No questions.

12          JUDGE MILLS: No other questions.

13          MR. GRON: All right, we ask that the Board reverse the  
14          Examiner's rejections in this case, because they are unreasonable; but more  
15          so because the Examiner's error in this case is that he refused to look at the  
16          evidence, as a whole.

17          And that, in itself, is a irreversible error.

18          JUDGE ADAMS: Okay. We'll take it under consideration.

19          (Whereupon, at 9:45 a.m., the proceedings were concluded.)

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